## GUIDE FOR REVIEWERS' PRELIMINARY COMMENTS ON MINORITY STUDENTS AND STUDENTS WITH DISABILITIES PREDOCTORAL FELLOWSHIP APPLICATIONS (F31)

In evaluating these predoctoral fellowship applications, the following items should generally be considered:

- The quality of the applicant's academic record and research experience and the relevance of the proposed training to the applicant's career goals.
- The quality and appropriateness of the proposed graduate or combined degree program.
- The training potential, including the scientific merit, significance, and originality, of the proposed thesis research (as applicable).
- The quality and appropriateness of the research mentor (if selected) or interim sponsor.

Neither an applicant's ethnic background, disability, nor the availability of other support (private, institutional, or federal) should influence assessment of the merit of these applications.

In preparing your written evaluation, use the REVIEW FORMAT as a guide. Please focus upon an overall assessment of the application and elaborate on particular strengths and weaknesses. Provide descriptive information on the training program and proposed research so that the other reviewers will understand the basis for your evaluation. Your comments will be transmitted to the applicant and institute staff with little or no additional editing by CSR staff. Please prepare your evaluations carefully, and be prepared to edit them to reflect any changes that occur as a result of discussion during the meeting.

Note that the applicants will range from those who are about to begin a graduate or combined degree program (and may or may not have chosen a thesis mentor) to those who are well along in their thesis research. Therefore, all of the items listed below may not be applicable in all cases. If there are additional items not listed which should be discussed in the review of the applications, they should be included in the written comments. Your overall evaluation of each application should be based on the criteria below.

### REVIEW FORMAT

**THE APPLICANT'S PREPARATION FOR GRADUATE STUDY,** including his/her academic record (grades, GRE or MCAT scores, honor/awards); letters of recommendation; previous research experience (including any presentations or publications and pertinence of the prior experience to this proposal); and training and career goals. Any special qualifications or unusual circumstances should be noted.

**THE QUALITY OF THE TRAINING PROGRAM / INSTITUTION**, including the appropriateness of the program and requirements to the applicant's training/career goals; the applicant's rationale for choosing the program; how well students are advised and their progress monitored; and, in the case of M.D./Ph.D. programs, any special features to facilitate the integration of, and transition between, the graduate and medical components.

**THE PROPOSED RESEARCH** (if a thesis topic has been chosen), focusing on its merit and training potential, taking into consideration the applicant's training career

goals; the significance and originality of the project and adequacy of the research plan and proposed methods; and the appropriateness of the relative contributions of the applicant and mentor in the preparation of the proposal. OR

**THE STATED RESEARCH INTERESTS OF THE APPLICANT** (for those who have not yet chosen a thesis topic), evaluated in terms of their appropriateness within the institutional setting and to the applicant's training/career goals.

**THE THESIS MENTOR** (if the applicant has chosen one), including the proposed mentor's qualifications and suitability to train the applicant based on the mentor's academic background, current position, research expertise, publication record, research support, and training experience. OR

**THE INTERIM SPONSOR** (if the applicant has not yet chosen a thesis advisor), including the appropriateness of the names sponsor in terms of guiding and monitoring the student's program/progress.

**OVERALL RECOMMENDATION** Indicate your overall level of enthusiasm (using the priority score guide) and recommend the length of support you feel is appropriate (provide a justification if different from the time requested).

**Human Subjects:** In applications with research proposals involving human subjects, consider the following:

**Are Human Subjects involved?** According to the new definition of human subjects, coded samples and data may not be considered human subjects use if they meet the criteria of:

a) the private information or specimens are not collected specifically for the proposed research through an interaction or intervention with living individuals,

b) the investigator cannot ascertain the identity of the individual to whom the coded private information or specimens pertain.

**Exemptions Claimed:** Express any comments or concerns about the appropriateness of the exemption(s) claimed. It should be noted that Exemption 4 is rarely used, as applications that qualified for E-4 under the old guidelines (specimens or data sets) will qualify as no human subjects if they meet the two conditions cited above.

**Protection of Human Subjects from Research Risks:** Evaluate the application with reference to the following criteria: risk to subjects, adequacy of protection against risks, potential benefit to the subjects and to others, importance of the knowledge to be gained. (If the applicant fails to address **all** of these elements, notify the SRA immediately to determine if the application should be withdrawn.) If all of the criteria are adequately addressed, and there are no concerns. Write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable. If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. If the application indicates that the proposed human subjects research is exempt from coverage by the regulations, determine if adequate justification is provided. If the claimed exemption is not justified, indicate "Unacceptable" and explain why you reached this conclusion. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRA immediately to determine if the application should be withdrawn.) Indicate

if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

**Inclusion of Women Plan:**
**Inclusion of Minorities Plan:**
**Inclusion of Children Plan:**
Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them. Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4. Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

| Category | Gender (G) | Minority (M) | Children (C) |
|---|---|---|---|
| 1 | Both Genders | Minority & non-minority | Children & adults |
| 2 | Only Women | Only minority | Only children |
| 3 | Only Men | Only non-minority | No children included |
| 4 | Gender unknown | Minority representation unknown | Representation of children unknown |
| 5 | | Only Foreign Subjects | |

**NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate.**

**Vertebrate Animals:** Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

**Biohazards:** Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

***Note**:* Sections on Vertebrate Animals, Human Subjects and Biohazards are to be included only when applicable.

**OTHER CONSIDERATIONS**: These comments are useful to NIH but should not influence your overall score.

**Foreign Training:** In a separate section, describe the scientific advantages of the proposed training in a foreign country and compare it to relevant training opportunities available in this country. Comment on any special talents, resources, populations, or environmental conditions that are not readily available in the United States or that augment existing resources. This consideration should not be factored into your overall recommendation and rating.

Further information about NIH research training opportunities can be found at http://grants.nih.gov/training

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